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TITLE: Using a bi-directional microscope: Enrolling activists as microbicide trial Participants

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ISSUE: Self-reported Phase I clinical trial data can be distorted when trial participants report what they think the researchers want to hear instead of their real experiences with trial products. Real and perceived power differentials between researchers and participants can give rise to such distortions in microbicide trials; where issues of product acceptability are being evaluated. Enrolling Phase I trial participants who feel comfortable in communicating openly with researchers may be one way to address this problem. Using educational strategies that enhance the level of knowledge among potential trial participants about microbicide trials and how they work may be another way.

SETTING: This project is undertaken in the Philadelphia, PA metropolitan area and involves recruitment from community based organizations providing HIV/AIDS-related and/or women's health care services, as well as local AIDS and women's health activist organizations.

PROJECT: By targeting Phase I trial participants from the above mentioned community segments and organizations, we hope to test a novel diffusion-based recruitment strategy. Women recruited from these pools are ideally situated to take information about microbicide trials back to their personal and professional networks. Because the people with whom they associate are likely to be receptive, we believe that this diffusion strategy will advance public awareness of microbicides and I prepare our community for any upcoming microbicide trial recruitment that may occur. By surveying both participants and research staff, we are also gathering qualitative data about the impact of this strategy on the research team. These data will help US begin to consider the question of whether working with knowledgeable, activist-oriented participants whose scrutiny effectively puts researchers under a microscope has any impact on the behaviors of the study team.

RESULTS: Our diffusion strategy is already yielding results. Twelve target organizations have requested in-service training on microbicide trials and our public Forum on the topic attracted 30 participants, as well as newspaper coverage. Our core recruitment activity has been two mailings to 250 targeted organizations with followup through assisted, toll-free telephone line. We have recruited 40 potential participants to date and anticipate no difficulty in fully enrolling both trials. By conference date, our trials will be at or near completion and a complete record of our recruitment experience, together with our qualitative data findings, will be available.

LESSONS LEARNED: This project will demonstrate a new strategy for recruitment for Phase I microbicide trials. It will provide a basis for further exploration of (1) this strategy's utility with regard to diffusing information effectively into target populations and (2) its potential impacts on study staff.

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